REMARKS

Claims 1-3 are pending in the instant application. Claims 1-3 have been rejected. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Objection of the Title of the Invention

The title of the invention has been objected to as not being clearly indicative of the invention to which the claims are directed. Applicants have amended the title to more clearly indicate the invention to which the claims are directed. Withdrawal of this objection is therefore respectfully requested.

II. Rejection of Claims Under 35 U.S.C. §103

The Examiner has maintained the rejection of claims 1-3 under 35 U.S.C. §103(a) as being unpatentable over Coligan et al. (Current Protocols in Immunology, Green Publishing Associates and Wiley-Interscience, New York, 1991; pages 2.1.1-2.1.3, 2.1.9-2.1.11, and 2.1.17-2.1.22) in view of U.S. Patent 5,077,216, and Zwaldo et al. (IDS Reference BA). The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the antibodies taught in the '216 patent and Zwaldo et al. in the ELISA taught by Coligan et al. to detect and monitor CD163 levels in a biological sample during an inflammatory condition/process by detecting CD163 as taught by Zwaldo et al. Further, the Examiner suggests that one of ordinary skill in the art would have been

motivated to substitute the antibodies taught in the '216 patent and Zwaldo et al. in the ELISA taught by Coligan et al. to detect and monitor CD163 because detecting CD163 levels can be used to monitor an inflammatory response cascade in a patient, as taught by Zwaldo et al.

Applicants respectfully traverse this rejection.

Applicants respectfully disagree with the Examiner's characterization of the teachings of Zwaldo et al. Contrary to the Examiner's suggestion, Zwaldo et al. does not teach monitoring the course of an inflammatory response cascade in a patient by detecting the levels of CD163. This reference teaches a monoclonal antibody (RM3/1) which detects a surface antigen which is preferentially expressed by macrophages appearing late in the inflammatory response in acute inflammatory tissue, e.g. gingivitis, and to varying degrees in chronic inflammation. Zwaldo et al. conclude that the RM3/1 antibody detects a macrophage phenotype which seems to be associated with the healing phase of the inflammatory process. In contrast, the instant specification teaches that CD163 is expressed early during the course of an inflammatory condition/process. Further, other than the expression patterns of the RM3/1 antigen, Zwaldo et al. do not provide any characterization of the RM3/1 antigen, e.g. molecular weight or sensitivity to trypsin, nor do the authors conclude that the RM3/1 antigen is the p155 protein, taught in the '215 patent, or CD163. Moreover, this reference does not teach or suggest the use of anti-CD163 antibodies in an ELISA assay to detect CD163 in a sample to monitor the course of an inflammatory response cascade.

While, the '216 patent teaches antibodies to p155, a human mononuclear phagocyte-specific cell-surface antigen, this patent does not teach or suggest that p155 is the RM3/1 antigen or CD163. Further, this reference does not teach or suggest the use of anti-CD163 antibodies in an ELISA assay to detect CD163 in a sample to monitor the course of an inflammatory response cascade.

Based only on the fact that p155, the RM3/1 antigen, and CD163 are cell-surface antigens, Applicants believe that the skilled artisan could not reasonably conclude that the RM3/1 antigen is p155 and that either of these proteins is CD163. Further, the expression patterns of the RM3/1 antigen and p155 would not provide a reasonable expectation that these two proteins were one and the same. Thus, there would be no suggestion or motivation as required under MPEP 2143.01 to combine these cited references with Coligan et al., which is a book chapter describing general protocols and uses of the ELISA assay method, to arrive at the claimed invention. It is only with the teachings of the instant specification that the skilled artisan would conclude that the RM3/1 antigen, p155 and CD163 are the same proteins and that CD163 would be useful in monitoring the course of an inflammatory response cascade in a patient. MPEP 2143 requires that an expectation of success be provided by the cited references alone, not in light of the teachings of the instant invention. Finally, as stated in MPEP 2143.01, the fact that references can be combined is not sufficient to establish *prima facie* obviousness. Accordingly, withdrawal of this rejection is respectfully requested.

III. Conclusion

The Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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Date: **June 23, 2003**

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